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| 09/422,046 | 10/20/1999 | STEPHEN J. BROWN | HERO-1-1025 | 5000 |

25315 7590 12/29/2003

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| EXAMINER |
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KALINOWSKI, ALEXANDER G

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| ART UNIT | PAPER NUMBER |
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3626

DATE MAILED: 12/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/422,046

Applicant(s)

BROWN, STEPHEN J.

Examiner

Alexander Kalinowski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 70-72, 74, 77, 81 and 82 is/are pending in the application.
- 4a) Of the above claim(s) 83-109 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 70-72, 74, 77, 81 and 82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 21. 6) ☐ Other: _____

DETAILED ACTION

1. Claims 70-72, 74, 77, and 81-109 are presented for examination. Applicant filed an amendment on 4/21/2003, filing a Rule 1.31 declaration and amending claims 70 and adding new claims 73-80. Applicant further filed an amendment on 10/23/2003, filing a new Rule 1.31 declaration and canceling claims 73, 75, 76, and 78-80, amending claims 70-72, 74, and 77, and adding new claims 81-109. After careful consideration of Applicant's amendment and arguments, the Examiner establishes new grounds of rejection of claims 70-72, 74, 77 and 81-82 based on limitations added by Applicant's amendments on 4/21/2003 and 10/23/2003 that were not present in the originally filed claims. The grounds of rejection of claims 70-72, 74, 77, and 81-82 are a final rejection of the claims and the new grounds of rejection were necessitated by Applicant's amendment to the claims.

Response to Amendment

2. The declaration filed on 10/23/2003 under 37 CFR 1.131 is sufficient to overcome the Fujimoto reference.

Response to Arguments

3. Applicant's arguments with respect to claims 70-72, 74, 77, and 81-82 have been considered but are moot in view of the new ground(s) of rejection.

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4. The Examiner acknowledges Applicant's reply to the request for information based on Rule 105 in the form of a Supplemental Information Disclosure Statement filed on 10/6/2003.

5. Newly submitted claim 83-109 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the newly submitted claims are directed to a blood glucose mentoring device that transmits digital blood glucose signals to a microprocessor based portable unit detecting a need for a change in insulin dosage. This invention is classified in class 600/300. The originally filed claims are directed to a patient interface for a patient monitoring device that transmits data signals to a central server and receives instructions to be responded to by the patient from the central server and classified in class 705/2. Examination of all the claims would place a serious burden on the Examiner. Therefore, the Examiner will examine the claims directed to the originally presented invention, namely, claims 70-72, 74, 77, and 81-82.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 83-109 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 70-72, 77, 81 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fu et al., Pat. No. 4,803,625 (hereinafter Fu) in view of .

As to claim 70, Fu discloses a patient interface system for use in collecting and transferring data from a patient to a remote monitor (Fig. 1 and abstract), said system comprising:

(a) a patient data receiver(see Figure 1, unit 60) including:

(i) a monitoring unit for monitoring a health related parameter and producing an indicia related to the measurement (i.e. temp module 86, scale module 84, blood pressure module 92, optional modules 94, ECG module 88)(Fig. 2, and col. 5, line 63 - col. 6, line 8); and

(ii) a patient interface including a display (Fig. 2);

(b) a processor (Fig. 2); and

c) a memory containing stored program instructions that

i) are operable by the processor to cause receipt and storage of data from the patient data receiver (Fig. 2, col. 8, lines 18-26 and col. 10, lines 28-48;

d) a communications link associated with the processor to

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i) facilitate transfer of the patient data to the central server (col. 4, lines 47-64 and col. 5, lines 47-48).

Fu does not explicitly disclose

enable the patient data receiver to remotely receive from a central server one or more queries to be answered by the patient and receive information to be responded to by the patient from the central server

However Kirk discloses enable the patient data receiver to remotely receive from a central sever one or more queries to be answered by the patient via the remote monitor (i.e. provide input to the health support system 10 ... health support system checks the wellness of a patient by monitoring the voice of the client in both prompted and unprompted exchanges)(col. 2, line 64 - col. 3, line 12). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include enable the patient data receiver to remotely receive from a central server one or more queries to be answered by the patient via the remote monitor as disclosed by Kirk within Fu for the motivation of providing a health care support system that economically provides medication control, wellness checking and patient data accumulation (col. 1, lines 52-60).

As to claim 71, Fu discloses the system according to claim 70, wherein said interrogation means further comprises a plurality of buttons (Fig. 2 and col. 5, lines 53-63).

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As to claim 72, Fu discloses the system according to claim 70, wherein said communication means comprises at least one of a modem and a serial interface (i.e. modem unit 62)(Fig. 1).

As to claim 77, Fu discloses the system of claim 70 wherein the remote patient data receiver subsystem further includes at least one monitoring device configured to

i) monitor at least one patient health condition (see Fig. 2 and col. 5, lines 7-32) and

ii) capture data relate to the monitored condition (see col. 5, lines 7-32).

As to claim 81, Fu discloses the system of claim 77, wherein the patient data receiver subsystem further includes at least one monitoring device configured to

i) monitoring at least one patient health condition and

ii) capture data related to the monitored condition.

As to claim 81, Fu discloses the system of claim 77, wherein at least one health related monitoring device includes one or more of the set consisting of

i) a blood glucose monitor;

ii) a peak flow monitor;

iii) a blood pressure monitor;

iv) a pulse monitor; and

v) a body temperature monitor (see col. 5, lines 27-32).

As to claim 82, Fu does not explicitly disclose the system of claim 70, further comprising at least one health care professional computer remotely located from and

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configured for signal communication with the central server to receive at least one report based on the patient health related data input.

However, Kirk discloses at least one health care professional computer remotely located from and configured for signal communication with the central server to receive at least one report based on the patient health related data input (see Fig. 1 and col. 5, lines 40-59). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include at least one health care professional computer remotely located from and configured for signal communication with the central server to receive at least one report based on the patient health related data input as disclosed by Kirk within Fu for the motivation of providing a health care support system that economically provides medication control, wellness checking and patient data accumulation (col. 1, lines 52-60).

8. Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fu and Kirk as applied to claim 70 above, and further in view of Dessertine, Pat. No. 5,016,172.

As to claim 74, Fu and Kirk do not explicitly disclose the system according to claim 70, wherein the stored programming instructions further enable the patient data receiver to present on the display a graphic representation of at least a portion of the patient data.

However, Dessertine discloses wherein the stored programming instructions further enable the patient data receiver to present on the display a graphic representation of at least a portion of the patient data (i.e. patient display unit 5)(col. 3,

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lines 61-64 and col. 4, lines 29-46 and 52-60). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein the stored programming instructions further enable the patient data receiver to present on the display a graphic representation of at least a portion of the patient data as disclosed by Dessertine within Fu and Kirk for the motivation of monitoring patient medication compliance and other patient characteristics remotely (col. 1, line 53 – col. 2, line 7).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander Kalinowski, whose telephone number is (703)

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305-2398. The examiner can normally be reached on Monday to Thursday from 9:00 AM to 6:30 PM. In addition, the examiner can be reached on alternate Fridays.

If any attempt to reached the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached on (703) 305-9588. The fax telephone number for this group is (703) 305-7687 (for official communications including After Final communications labeled "Box AF").

Hand delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, 7th Floor, receptionist.

A handwritten signature in black ink, appearing to read "Alexander Kalinowski". The signature is fluid and cursive, with a large initial 'A' and a stylized 'K'.

Alexander Kalinowski

Primary Examiner

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12/28/03